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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/586,890

07/21/2006

Hansell H. Stedman

UPN-Q3355USA

1686

270 7590 06/03/2009

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EXAMINER

NOAKES, SUZANNE MARIE

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

06/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/586,890	Applicant(s) STEDMAN ET AL.	
	Examiner SUZANNE M. NOAKES	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10, 12 and 19-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 12, 19-23, 25 and 26 is/are rejected.
- 7) ☒ Claim(s) 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07/21/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/18/06 & 02/11/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II or III in the reply filed on 06 April 2009 is acknowledged. The traversal is on the ground(s) that Applicants erroneously did had claims 10 and 12 depend from cancelled claims and have subsequently amended the claims to clarify this ambiguity. As such, the intent and scope of the claims for Groups II and III are now one and the same. This is found persuasive and thus the restriction requirement between Groups II and III is withdrawn.

Status of the Claims

2. The amendments filed 06 April 2009 are acknowledged. Applicants have cancelled claims 1-9, 11, 13-18 and added new claims 21-26 which are commensurate in scope with claim 19. As such, claims 10, 12 and 19-26 are pending and subject to examination on the merits.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 11 February 2008 and 18 October 2006 have been considered by the examiner. See initialed and signed PTO-1449's.

Specification

4. The disclosure is objected to because of the following informalities: Under the Brief Description of the Drawings section, the description for Figure 3 is for Figures “3A to 2K”, rather than “3K” – see p. 2, line 19..

Appropriate correction is required.

Claim Rejections - 35 USC § 112 – 2nd paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 states that the microutrophin comprises an internal deletion of the native utrophin protein of hinge region 3. However, the specification, for instance, notes that human microutrophin only possesses two hinge regions (see specification, p. 4, lines 13-14). Van Deutekom (Figure 1, p. 786 – reference cited on IDS from 02/11/2008) also suggests there are only two hinge regions in the highly conserved utrophins. While, the specification further states there might be up to four hinge regions (see specification, p. 4, lines 1-9), said specification gives no guidance whatsoever as to where these regions might be. Thus, given contrary guidance in the specification and in the prior art, what “hinge region 3” even is, is not apparent.

Claim Rejections - 35 USC § 112 – 1st paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 10, 12, 19-23, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a vector comprising a "microtrophin" under the control of regulatory sequences which direct its expression in a host cell. The term "microtrophin" is somewhat defined in the specification as follows:

The "microtrophin" of the invention is a utrophin polypeptide having a functional portion of the "actinin-binding domain" of about 270 amino acids relative to the human utrophin which is located within the N-terminal utrophin region, at least functional portions of the proline-rich hinge regions 1 and 4 (H1) and (H4); and a portion of the C-terminal utrophin protein. The microtrophin contains internal deletions in the central rod repeat domains and a truncation in the C-terminal region downstream, but retains the proper phasing (i. e., conformation) to retain the desired biological function of utrophin. (see specification, p. 4, lines 1-9)

It is noted that Utrophin is a protein which has 3,433 amino acids in its mature, full-length form. As to what exactly constitutes hinge region 4, the Examiner is not sure because while the closely related dystrophin has four hinge regions, the prior art clearly states and suggests (as does the instant specification) that utrophin has only two hinge regions (see

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112 2nd rejection above). Nonetheless, the interpretation of "microtrophin" given its meaning/definition in the claims clearly envisages and encompasses a huge genus of nucleic acid molecules encoding for shortened utrophins with internal deletions and no clear boundaries for the N- or C-terminus. However, the specification only provides for three species, SEQ ID NO: 2, 4 and 5 (canine, human and mouse microtrophin, respectively) of the very broad and structurally diverse genus of molecules which also do retain the desired biological function of utrophin.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, at the time the invention was made, of the specific subject matter claimed. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that 'the inventor invented the claimed invention.'" *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those

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specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...) *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

MPEP § 2163 further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." Furthermore, the courts have also held that possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features. *See University of Rochester*, 358 F.3d at 927, 69 USPQ2d at 1895.

In the instant case, as noted, the genus of molecules encompassed within the various vectors is enormous. While the claims do not recite that said vectors retain any particular biological function, the definition of "microutrophin" within the specification clearly establishes that the biological function of utrophin is retained. However, given the lack of representative species for this extensive and variable genus, it is clear Applicants are not in possession of the genus and as such the claims lack written description to be able to claim such an extensive genus.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 19, 21-23, 25 and 26 are rejected 35 U.S.C. 102(a & e) as anticipated by Tinsley et al. (US 6,518,413 – cited on IDS from 10/18/2006).

Tinsley et al. teach a DNA molecule that is a utrophin "mini-gene" which expresses a polypeptide that encodes for a 2008 amino acid protein which possesses the N-terminal amino acid domain, and the C-terminal amino acid domain, but which is missing the majority of the central domain (approximately 1500 amino acids – attached amino acid sequence alignment of instant SEQ ID NO: 5 and SEQ ID NO: 8 of Tinsley et al. – also see SCORE, .rai file, Result 2). The polynucleotide is cloned and is placed under the control of the human skeletal alpha-actin (HAS) promoter and regulatory regions (column 16, lines 55-62). This promoter is a muscle specific promoter. The DNA of the invention contained within adenovirus or retrovirus vectors (column 10, lines 1-3, col. 13, lines 17-19 and claims 22 and 23) and is specifically cloned into vector SV40 under the control of the promoter HAS (See Example 1). Claims 21 and 23 are included in this rejection because the prior art suggests/teaches that utrophin only has two hinge regions as noted above. Thus, it is

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deemed that Tinsley et al., SEQ ID NO: 8 meets the definition of microutrophin as defined within the instant specification.

Tinsley et al. further teach nucleic acid according to the present invention may form part of a cloning vector and/or a vector from which the encoded polypeptide may be expressed. Suitable vectors can be chosen or constructed, containing appropriate and appropriately positioned regulatory sequences, including promoter sequences, terminator fragments, polyadenylation sequences, enhancer sequences, marker genes and other sequences as appropriate. Vectors may be plasmids, viral e.g. phage, or phagemid, as appropriate. For further details see, for example, Molecular Cloning: a Laboratory Manual: 2nd edition, Sambrook et al., 1989, Cold Spring Harbor Laboratory Press. (see col. 7, lines 26-37).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 10, 12 and 20 are rejected under 35 U.S.C. 102(a & e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Tinsley et al. (US 6,518,413 – cited on IDS from 10/18/2006) as recited above for claims 19, 21-23, 24 and 25.

Tinsley et al. teach a DNA molecule that is a utrophin "mini-gene" which expresses a polypeptide that encodes for a 2008 amino acid protein which possesses the N-terminal

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amino acid domain, and the C-terminal amino acid domain, but which is missing the majority of the central domain (approximately 1500 amino acids – attached amino acid sequence alignment of instant SEQ ID NO: 5 and SEQ ID NO: 8 of Tinsley et al. – also see SCORE, .rai file, Result 2). The polynucleotide is cloned and is placed under the control of the human skeletal alpha-actin (HAS) promoter and regulatory regions (column 16, lines 55-62). This promoter is a muscle specific promoter. The DNA of the invention contained within adenovirus or retrovirus vectors (column 10, lines 1-3, col. 13, lines 17-19 and claims 22 and 23) and is specifically cloned into vector SV40 under the control of the promoter HAS (See Example 1). Claims 21 and 23 are included in this rejection because the prior art suggests/teaches that utrophin only has two hinge regions as noted above. Thus, it is deemed that Tinsley et al., SEQ ID NO: 8 meets the definition of microutrophin as defined within the instant specification.

Tinsley et al. further teach nucleic acid according to the present invention may form part of a cloning vector and/or a vector from which the encoded polypeptide may be expressed. Suitable vectors can be chosen or constructed, containing appropriate and appropriately positioned regulatory sequences, including promoter sequences, terminator fragments, polyadenylation sequences, enhancer sequences, marker genes and other sequences as appropriate. Vectors may be plasmids, viral e.g. phage, or phagemid, as appropriate. For further details see, for example, Molecular Cloning: a Laboratory Manual: 2nd edition, Sambrook et al., 1989, Cold Spring Harbor Laboratory Press. (see col. 7, lines 26-37).

Also taught is (see specification, col. 8, lines 47-62):

Polypeptides and nucleic acid according to the invention may be used in the manufacture of medicaments, compositions, including pharmaceutical formulations, and drugs for delivery to an individual, e.g. a human with muscular dystrophy or a non-human mammal, such as a mouse, as a model for study of the polypeptides, muscular dystrophy and therapy thereof.

For example, a method of treatment practised on the human or animal body in accordance with the present invention may comprise administration to an individual of nucleic acid encoding a polypeptide as disclosed herein. The nucleic acid may form part of a construct enabling expression within cells of the individual. Nucleic acid may be introduced into cells using a retroviral vector, preferably one which will not transform cells, or using liposome technology.

AND (see col. 9, lines 7-16):

Pharmaceutical compositions according to the present invention, and for use in accordance with the present invention, may comprise, in addition to active ingredient, a pharmaceutically acceptable excipient, carrier, buffer, stabiliser or other materials well known to those skilled in the art. Such materials should be non-toxic and should not interfere with the efficacy of the active ingredient. The precise nature of the carrier or other material will depend on the route of administration, which may be oral, or by injection, e.g. cutaneous, subcutaneous or intravenous.

AND: (see specification, col. 10, lines 1-8)

Adenoviral, retroviral or other viral vectors may be used advantageously for the introduction of a utrophin sequence according to the present invention into muscle cells. Even though in vivo transduction may be restricted to growing or regenerating muscle fibres, retrovirally introduced constructs have the advantage of becoming integrated into the genome of the host cell, potentially conferring lifelong expression.

Thus, while Tinsley et al. do not teach the utrophin-minigene of SEQ ID NO: 8 in a vector which is a pharmaceutical composition *per se*, it is clearly taught and suggested that said sequence can be incorporated into such a vector which is used in a pharmaceutical composition.

Tinsley et al. (SEQ ID NO: 8) and Instant SEQ ID NO: 5 sequence alignment

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RESULT 2
US-09-091-501B-8
; Sequence 8, Application US/09091501B
; Patent No. 6518413
; GENERAL INFORMATION:
; APPLICANT: Tinsley, Jonathon M
; APPLICANT: Davies, Kay E
; TITLE OF INVENTION: Utrophin gene expression
; FILE REFERENCE: 620-42
; CURRENT APPLICATION NUMBER: US/09/091,501B
; CURRENT FILING DATE: 1998-06-18
; PRIOR APPLICATION NUMBER: PCT/GB96/03156
; PRIOR FILING DATE: 1996-12-19
; PRIOR APPLICATION NUMBER: GB 9525962.8
; PRIOR FILING DATE: 1995-12-19
; PRIOR APPLICATION NUMBER: GB 9615797.9
; PRIOR FILING DATE: 1996-07-26
; PRIOR APPLICATION NUMBER: GB 9622174.2
; PRIOR FILING DATE: 1996-10-24
; NUMBER OF SEQ ID NOS: 15
; SOFTWARE: PatentIn Ver. 2.1
; SEQ ID NO 8
; LENGTH: 2008
; TYPE: PRT
; ORGANISM: Artificial Sequence
; FEATURE:
; NAME/KEY: misc_feature
; LOCATION: (239) ... (250)
; OTHER INFORMATION: Description of Artificial Sequence: Chimeric; Xaa =
Unknown
US-09-091-501B-8

Query Match          90.3%; Score 5447.5; DB 2; Length 2008;
Best Local Similarity 63.9%; Pred. No. 0;
Matches 1111; Conservative 16; Mismatches 34; Indels 579; Gaps 2;

Qy      1 MAKYGDLEARPDDGQNEFSDIKSRSDVQKKTFQKWINARFSKSGKPPISDMFSDL 60
        |||||: || ||:|||||||:|||||||
Db      1 MAKYGEHEASPDNGQNEFSDIIESRSDVQKKTFQKWINARFSKSGKPPISDMFSDL 60

Qy      61 KDGRKLLDLLEGLTGTSPLKRGSTRVHALNNVNRVLQVLHQNNVDLVNIGGTDIVAGNP 120
        |||||
Db      61 KDGRKLLDLLEGLTGTSPLKRGSTRVHALNNVNRVLQVLHQNNVDLVNIGGTDIVDGNP 120

Qy      121 KLTGLLLWSIILHWQVKDVMKDIMSLLQQTNSEKILLSWVRQTRPYSQVNVNFTTSWT 180
        |||||
Db      121 KLTGLLLWSIILHWQVKDVMKDIMSLLQQTNSEKILLSWVRQTRPYSQVNVNFTTSWT 180

Qy      181 DGLAFNAVLHRHKPDLEFDWDEMVKMSPIERLDHAFDKAHTSLGIEKLLSPETVAVHLPPDK 240
        |||||
Db      181 DGLAFNAVLHRHKPDLEFSWDRVVKMSPIERLEHAFKAHTYLGIEKLLDPEDVAVHLPXX 240
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Qy	241	KSIIIMYLTSLFEVLPQQVTIDAIREVETLPRKYKKECEEEIHIQSAVLAEEGQSPRAET	300
Db	241	XXXXXXXXXXVEVLPQQVTIDAIREVETLPRKYKKECEEEIHIQSAVLAEEGQSPRAET	300
Qy	301	PSTVTEVDMDLDSYQIALEEVLTWLLSAEDTFQEQHDISDDVEEVKEQFATHETFMMELT	360
Db	301	PSTVTEVDMDLDSYQIALEEVLTWLLSAEDTFQEQDDISDDVEEVKEQFATHETFMMELT	360
Qy	361	AHQSSVGSVLQAGNQLMTQGTLSREEEFIEIQEQMTLLNARWEALRVESMERQSRLHDALM	420
Db	361	AHQSSVGSVLQAGNQLMTQGTLSREEEFIEIQEQMTLLNARWEALRVESMERQSRLHDALM	420
Qy	421	ELQKKQLQQLSWLALTEERIQKMESLPLGDDLPSLQKLLQEHKSLQNDLEAEQVKVNSL	480
Db	421	ELQKKQLQQLSWLALTEERIQKMESLPLGDDLPSLQKLLQEHKSLQNDLEAEQVKVNSL	480
Qy	481	THMVVIVDENSGESATALLEDQLQKLGERWTAVCRWTEERWNRLQEISILWQELLEEQCL	540
Db	481	THMVVIVDENSGESATALLEDQLQKLGERWTAVCRWTEERWNRLQEISILWQELLEEQCL	540
Qy	541	LEAWLTEKEEALDKVQTSNFKDQKELSVSVRRLAILKEDMEMKRQTLQDLSEIGQDVGQL	600
		:	
Db	541	LEAWLTEKEEALNKVQTSNFKDQKELSVSVRRLAILKEDMEMKRQTLQDLSEIGQDVGQL	600
Qy	601	LSNPKASKKMNSDSEELTQRWDSLVRLEDSSNQVTQAVAKLGMSQIPQKDLLETVHVRE	660
Db	601	LSNPKASKKMNSDSEELTQRWDSLVRLEDSSNQVTQAVAKLGMSQIPQKDLLETVHVRE	660
Qy	661	QGMVKKPKQELPPP-----	674
		:	
Db	661	KGMVKKPKQELPPPLTKAEHAMQKRSTTELGENLQELRDLTQEMEVHAEKWKWLNRTLE	720
Qy	675	-----	674
Db	721	MLSDKSLSLPERDKISESLRTVMNTWNKICREVPTTLKECIQEPSSVSQTRIAAHPNVQK	780
Qy	675	-----	674
Db	781	VVLVSSASDIPVQSHRTSEISIPADLDKTITELADWLVLIDQMLKSNIVTVGDVEEINKT	840
Qy	675	-----	674
Db	841	VSRMKITKADLEQRHPQLDYVFTLAQNLKNKASSSDMRTAITEKLERVKNQWDGTQHGVE	900
Qy	675	-----PPPK-----	678
Db	901	LRQQQLEDMIIDSLQWDDHREETEELMRKYEARELYILQQARRDPLTKQISDNQILLQELG	960
Qy	679	-----	678
Db	961	PGDGIVMAFDNVLQKLLEEYGSDDTRNVKETTEYLKTSWINLKQSIADRQNALEAEWRTV	1020
Qy	679	-----	678

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Db 1021 QASRRDLENFLKWIQEAETTVNVLVLDASHRENALQDSILARELKQQMQDIQAEIDAHNDI 1080

Qy 679 ----- 678

Db 1081 FKSIDGNRQKMVKALGNSEEATMLQHRLDDMNQRWNDLKAKSASIRAHLEASAEKWNRL 1140

Qy 679 ----- 678

Db 1141 MSLEELIKWLNMKDEELKKQMPIGGDVPALQLQYDHCKALRRELKEKEYSVLNAVVDQARV 1200

Qy 679 -----KRQ 681
::|

Db 1201 FLADQPIEAPEEPRRNLSKTELTPEERAQKIAKAMRKQSSEVKEKWESLNAVTSNWQKQ 1260

Qy 682 IHVDLEKLRLDLQGAMDDLADMKVEEAVRNGWKPVGDLLIDSLQDHIEKTAFREEIAPI 741
: |||||:|||||:|||||:|||||

Db 1261 VDKALEKLRLDLQGAMDDLADMKAEESVRNGWKPVGDLLIDSLQDHIEKIMAFREEIAPI 1320

Qy 742 NLKVKTMDLSSQLSPLDLHPSLKMSRQLDDLNRWKLLQVSVDDRLKQLQEAHRDFGPS 801
| ||||:|||||:|||||:|||||

Db 1321 NFKVKTVNDLSSQLSPLDLHPSLKMSRQLDDLNRWKLLQVSVDDRLKQLQEAHRDFGPS 1380

Qy 802 SQHFLSTSVQLPWQRSISHNKVPYYINHQTQTTCWDHPKMTLQSLADLNNVRFSAYRT 861
|||||:|||||:|||||:|||||

Db 1381 SQHFLSTSVQLPWQRSISHNKVPYYINHQTQTTCWDHPKMTLQSLADLNNVRFSAYRT 1440

Qy 862 AIKIRRLQKALCLDLLELNTTNEVFKQHKLQNDQLLSVPDVINCLTTTYDGLQLHKDL 921
|||||:||||:|||||:|||||:|||||

Db 1441 AIKIRRLQKALCLDLLELSTTNEIFKQHKLQNDQLLSVPDVINCLTTTYDGLQMHKDL 1500

Qy 922 VNVPLCVDMLNWLNNVYDTGRTGKIRVQSLKIGLMSLSKGLLEEKYRCLFKEVAGPTM 981
|||||:|||||:|||||:|||||

Db 1501 VNVPLCVDMLNWLNNVYDTGRTGKIRVQSLKIGLMSLSKGLLEEKYRYLFKEVAGPTM 1560

Qy 982 CDQRQLGLLLHDAIQIPRQLGEVAAFSGSNIEPSVRSCFQQNNNKPEISVKEFIDWMHLE 1041
|||||:|||||:|||||:|||||

Db 1561 CDQRQLGLLLHDAIQIPRQLGEVAAFSGSNIEPSVRSCFQQNNNKPEISVKEFIDWMHLE 1620

Qy 1042 PQSMVWLPVLRVAAAETAKHQAKCNICKECPVGFYRSLKHFNYDVCQSCFFSGRTAK 1101
|||||:|||||:|||||:|||||

Db 1621 PQSMVWLPVLRVAAAETAKHQAKCNICKECPVGFYRSLKHFNYDVCQSCFFSGRTAK 1680

Qy 1102 GHKLHYPMVEYCIPTTSGEDVRDFTKVLKNKFRSKKYFAKHPRLGYPVQTVLEGDNLET 1161
|||||:|||||:|||||:|||||

Db 1681 GHKLHYPMVEYCIPTTSGEDVRDFTKVLKNKFRSKKYFAKHPRLGYPVQTVLEGDNLET 1740

Conclusion

13. Claims 10, 12, 19-13, 25 and 26 are rejected. Claim 24 is objected to but would be allowable if rewritten in independent form.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE M. NOAKES whose telephone number is (571)272-2924. The examiner can normally be reached on 7.00 AM-3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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